Amendment #2 (Questions & Responses)

ALSO: PLEASE NOTE CHANGE TO PAGE LIMITATIONS

to RFP-NIH-NIAID-DAIDS-03-25

"HIV Clinical Research Management Support"

Amendment to Solicitation No.:	NIH-NIAID-DAIDS-03-25
Amendment No.:	**2**
Amendment Date:	**August 15, 2002 (Question 1)** **September 16, 2002 (Questions 2 – 18)** **October 4, 2002 (Questions 19 -32)**
RFP Issue Date:	July 22, 2002
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Point of Contact:	Barbara Shadrick bs92y@nih.gov Senior Contracting Officer
Name and Address of Offeror:	To All Offerors

PAGE LIMITATIONS FOR TECHNICAL PROPOSAL – REVISED FROM 100 PAGES TO NOT-TO-EXCEED 150 PAGES: The reference to page limitations on the cover page of the RFP and on page 31 of the RFP ("How to Prepare and Submit an Electronic Proposal") is revised to limit the total number of pages for the Technical Proposal to not-to-exceed 150 pages. This includes all information from cover-to-cover in the Technical Proposal.

THE HOUR AND DATE SPECIFIED FOR RECEIPT OF OFFERS IS NOT EXTENDED AND REMAINS AT OCTOBER 22, 2002, 4:00 PM, EST.

OFFERORS MUST ACKNOWLEDGE RECEIPT OF THIS AMENDMENT #2 ON EACH COPY OF THE OFFER SUBMITTED. FAILURE TO RECEIVE YOUR ACKNOWLEDGMENT OF THIS AMENDMENT MAY RESULT IN THE REJECTION OF YOUR OFFER.

THIS AMENDMENT PROVIDES QUESTIONS SUBMITTED BY OFFERORS AND THE RESPONSES PROVIDED BY THE NIAID PROJECT OFFICER. ANY FURTHER QUESTIONS AND THEIR RELATED RESPONSES WILL BE ADDED TO THIS AMENDMENT UPON RECEIPT. ALL OFFERORS SHOULD REFER BACK TO THIS AMENDMENT #2 FOR ADDITIONAL QUESTIONS AND RESPONSES.

Below are the Questions and Responses issued on August 15, 2002:

Question 1 The RFP states that "Offerors will be evaluated on staff and expertise in the conduct of large trials in resource-constrained areas such as Asia, Africa, Eastern Europe and India." Is the contract limited to these geographical areas or are these just examples? Would trials possibly be conducted in Latin America or South America?

This contract will focus on the areas identified in the RFP. The HIV Vaccine Trials Network does have a large presence in South America -- please see: http://www.hvtn.org/. It may be possible that as the network gets busier they may need assistance in the Americas although the other areas identified in the RFP are the areas of priority.

Below are the Questions and Responses issued on September 16, 2002:

Question 2. Please offer more detail regarding the expectations of the call center functionality.

The Call Center would handle many different types of logistical items in support of clinical trials. Personnel would track site registration materials (IRB approvals, CV, Lab normals), and would have systems in place to communicate with the PI to inform of missing items, to communicate that a site is ready to go or that a site must stop for special reasons. Additionally, this Call Center would be utilized for other tasks such as answering questions from PIs (such as what a study is about in case they would like to consider participating), general questions about a trial, as well as act as a first line recruiting tool for volunteers. In the case of volunteers, they would be given a 1-800 number to pre-screen volunteers, then pass this information to study coordinators in the volunteers catchment area. If a trial requires a diary, the Call Center could utilize an IVRS system to capture diary answers. Other uses of the may include using IVRS to randomize. The also may be utilized for expanded access or follow-on Phase IV studies to capture safety information. This Center will also be responsible for interfacing with the core management group in order to assemble binders that will be required for each study, thereby serving as a distribution center. It will be important that the offeror have the ability to set up such an operation in Europe or Africa or Asia to allow access for international studies (only one region may be necessary). International Call Centers must be bi-lingual. A Domestic Call Center must be able to offer Spanish for Spanish- speaking callers.

Question 3. Please clarify whether the bid is only for consultation or for consultation and site audits.

This is for both consultation and for site audits. Offerors must be able to QA their own monitors as well.

Question 4. Section B., Page 9 of the Statement of Work states:

d. Design web mechanisms to electronically track site visit problems/resolution(s) with the ability to report on the status of such problems/resolutions.

Does DAIDS expect development of a validated system with a dedicated server and interactive capabilities between the Contractor and DAIDS for communication of these problems/resolutions?

Yes

Question 5. Section 1.a) The request for proposal states that NIH wants a database developed using commercial off-the-shelf software. Can this be something developed with a product such as Oracle or does the NIH want a vendor's (commercial off-the-shelf) product?

NIH must be able to utilize the database after the contract is finished. Therefore, off the shelf software is the only option that we are aware of that will allow us to utilize such databases after the contractor is no longer involved.

"Access to these databases shall be given to the DAIDs." - Does this mean NIHwants to be able to log into the system or is it in terms of ownership (access to the information)?

Yes

Question 6. "Additionally the contractor shall provide, at a minimum, the following activities:

1.2) "transfer legacy data into new databases" - Does NIH have study data in other databases currently? Will there be data migration?

Yes to both questions.

Question 7. 1.5) "provide enterprise capabilities to integrate and to have interoperability of the databases under this contract" - Define what is meant by enterprise capabilities. Do we need to interface with other systems? Do we need to exchange with others?

DAIDS will be implementing an Enterprise System to integrate multiple database here at DAIDS and held by DAIDS contractors. New contractors will be expected to interface with this system, i.e., give access to their database to the Enterprise System.

Question 8. 2.a.) "Use www.clinicaltrials.gov to establish an interface to produce protocol activity reports that will include protocol summaries and accrual to date information as well as site participation information." - There doesn't appear to be any security on this web site. Is this secured information? Direct Connect is another option. If we provide this information, does it need to be automated as an interface or a report that will be produced? Will someone be entering it into the NIH system?

This is not secured information as the purpose of the website is to inform the public. The contractor will need to work with the National Library of Medicine to enter the protocol summaries. The Project Officer will facilitate this action.

Question 9. 3.a.) "Provide IT systems to facilitate trial implementation and trial management." - What does this include?

It means that we expect state-of-the-art IT systems that will facilitate trial implementation and trial management, such as web-based systems. There are many systems advertised which facilitate this.

Question 10. Does NIH want hardware and infrastructure also?

Yes, we will need hardware at developing country sites when needed. We cannot predict this so we gave an assumption to all offerors in the RFP. We would need more detailed requirements. Those will be provided when we know what the needs are.

Question 11. Is this software programs, printers, LANs for the remote locations?

Yes, these are good examples. Additionally, we may need laptops, PDAs, Blackberries, all items that will facilitate communication and enhance IT capabilities in developing countries.

Question 12. 3.b.) "Propose web-based systems and innovative IT options for trial management such as Personal Digital Assistants and Other wireless technologies." - Is this for the subjects or staff?

Primarily for staff, we could use web for recruitment of subjects.

Question 13. Would NIH be supplying the hardware? Currently we do not have a system in place that supports this but we are looking at some options. We would need more information on how NIH plans to use this.

No. For communication with study personnel and even for CRF entry and monitoring, dependent upon the system proposed. The more we can utilize web-based technology, the better.

Question 14. If the country is resource-constrained, will we need to set up the networks and connections to systems?

Yes.

Question 15. Will the countries have the capability to use this type of hardware if the they are resource-constrained or will it not be feasible or at risk of loss, etc?

We will expect the contractor to place mechanisms in place to reduce risk of loss. If it is lost, then insurance with the offeror should cover this.

Question 16. 3.d.) "Propose and utilize mechanisms such as PC based web meetings, internet facilitated meetings and videoconferencing capabilities to enhance communication and decrease Investigator travel." - We do have the capability to provide videoconferencing and could get the resources for web/net meetings, but again will there need to be resources provided to the countries and will this cost be factored in?

The offeror should factor this cost in to their proposals with assumptions noted.

Question 17. Data Management: Translations - It sounds like we be expected to provide CRFs in several languages so the site can complete them in their native language. We then will need to translate the data on the CRFs (responses) back into English. I know there are companies that provide this service, however, I do not know first hand who they are or the costs associated... will it be ok for us to assume English and provide an estimate for translations later? Or on a T&M basis?

It would be best to provide an estimation of costs with the proposal. If this is impossible, please note that it will be provided later. The is a cost-reimbursable contract.

Question 18. We are asked to "accommodate special and routine data processing requests and data transfers". We will need to ensure we provide costs for reports and transfers on a "per request" basis. (DM and Programming/Bios)

Yes.

Below are the Questions and Responses issued on October 4, 2002:

Question 19. Does NIAID expect that the Contractor will act as a pass through for payments to clinical sites? Or will sites have an independent mechanism to receive funds from the government or other trial sponsor?

This will be dependent upon the type of site. If the site is already a site participating within a network, the site may already have mechanisms in place. In addition, it is possible that sites may receive payment directly from industry. The DAIDS would like to have this contract function as much as possible as a "CRO" type model, therefore mechanisms to address the "pass thru" scenario will be needed.

Question 20. Could you supply more guidance regarding the distinction between the "Technical Proposal Cost Information" and "Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours (applicable to the business proposal)?" (see RFP p. 29) In particular, can you offer guidance as to how much (if any) information regarding the assumptions and costing of the Phase III trial and stand alone tasks (see RFP pp 19-20) should appear in the technical proposal vs the business proposal?

The major distinction is that the Technical Proposal format does not provide indirect and fee information. The outside peer reviewers are not provided with organizations' private rate information. The information in paragraphs 1. and 2. should be submitted with the Technical Proposal.

Question 21. Does the government expect that any of the trial activities supported through this contract will occur domestically? If yes, could you estimate a proportion of the trials that would be implemented domestically?

Yes. For purposes of cost estimation, one could estimate that 25% of the work will be domestic and 75% international.

Question 22. The documentation necessary to fulfill the government regulations with respect to IT systems security (OMB A-130 and DHHS Program Handbook – see RFP p. 62) typically fills many (20+) pages. Is it permissible to reference this document as an appendix to the technical proposal that would not count against the 100 page limit, or, alternatively, to include this documentation in the business proposal? Can we assume that front matter does not count against this page limitation? Will the Government consider excluding resumes from the 100 page limit for the Technical Proposal?

Yes. We will be increasing the page limits to a total of 150 pages. This will include all information provided from cover-to-cover of the Technical Proposal. See the information provided at the top of this Amendment #2.

Question 23. Who will be the primary contact for this RFP?

I am the only contact for this RFP. The Project Officer cannot be identified and cannot communicate directly with any offeror during the solicitation process. Once negotiations begin, the Project Officer will participate in negotiations but only with a Contracting Officer present.

Question 24. What will be the role of DAIDS?

The DAIDS will take the lead in directing this project. The Project Officer will authorize utilization of resources for this contract.

Question 25. What will be the approval procedure (e.g., protocols, forms, training materials)?

The contractor will work with DAIDS to establish an approval procedure. DAIDS will have final approval.

Question 26. How will protocols be generated?

The contractor will write the protocol, manage the process and elicit input from DAIDS and others, utilizing a CRO type model.

Question 27. Page 19 of the RFP, entitled "Notes to Offerors and Additional Technical Proposal Instructions," requests an estimate for a Phase III trial. Is this estimate to be included in the technical proposal only?

Yes.

Question 28. Page 20 of the RFP, paragraph 2 "Offeror Costing of Stand Alone Tasks," requests a cost estimate for each of 13 tasks. Are these estimates to be included in the technical proposal only?

Yes.

Question 29. A five-year estimate is to be provided in the Business proposal, using the estimated level of efforts from Section L, paragraph d and infrastructure estimate from page 20. Is the direct cost portion of our five-year estimate to be included in the technical proposal?

Yes. Use the attachment entitled "Technical Proposal Cost Information" identified on page 29.

Question 30. Section L, page 39, paragraph d, provides an estimated level of effort for Year 1 and then subsequent estimated increases for portions of the effort in years 2 through 5. Are the estimated increases noted for years 3, 4 and 5, increases over year 1 or increases over the previous year. In other words, is the estimated 65% increase in year 3, 65% of the year 2 estimate or the year 1 estimate?

These percentages represent an increase to the previous year's estimate.

Question 31. Page 56 of the RFP, entitled "Salary Rate Limitation in Fiscal Year 2003," advises that NIH will not pay the direct annual salary of an individual at a rate in excess of the Executive Schedule, level I. The rate for FY2003 is still pending legislation, but the FY2002 rate was $166,700. Many of the professionals that are required in performance of this effort have a high level of expertise and medical and/or scientific credentials. In order to allow for staffing at the caliber necessary to effectively mitigate project risk and ensure successful trial management, will the Government consider waiving the Salary Rate Limitation included in the RFP?

This ceiling is set by Public Law. There are no waivers. All Contractor's must comply.

Question 32. Please provide a list of all organizations that submitted Letters of Intent to Bid and identify subcontractors if identified.

We are prohibited by regulation to identify the competition under the acquisition process.

[END OF AMENDMENT #2]